JC18 Rec'd PCT/PTO 31 JUL 2001

Form PTO 1390 (REV 5-93) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER
		C70376
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED / ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) 09/890387
INTERNATIONAL APPLICATION NO. PCT/EP00/00559	INTERNATIONAL FILING DATE 26 January 2000	PRIORITY DATE CLAIMED 02 February 1999
TITLE OF INVENTION CONTAINER WITH SPACED APART LABEL		
APPLICANT(S) FOR DO/EO/US Harry FLEWITT		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1 [x] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.

2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.

3. [x] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).

4. [x] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. [x] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).

6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. [x] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [x] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.

8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S. C. 371(c)(3)).

9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. [x] An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; and Form PTO-1449.

12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.

13. [x] A FIRST preliminary amendment.

14. [ ] A SECOND or SUBSEQUENT preliminary amendment.

15. [x] Please amend the specification by inserting before the first line the sentence: This is a 371 of International Application PCT/EP00/00559, filed 26 January 2000, which claims benefit from the GB 9902138.8 filed 02 February 1999.

16. [ ] A substitute specification.

17. [ ] A change of power of attorney and/or address letter.

18. [x] An Abstract on a separate sheet of paper.

19. [ ] Other items or information:

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US APPLICATION NO. (if known, see 37 CFR 1.50)	INTERNATIONAL APPLICATION NO.	ATTORNEYS DOCKET NO.
09/890387	PCT/EP00/00559	C70376

20. [X] The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 C.F.R. 1.492(a)(1)-(5)):		
Search Report has been prepared by the EPO or JPO **$860.00**	**860.00**	
International Preliminary Examination Fee paid to USPTO (37 CFR 1.482) **$690.00**		
No International Preliminary Examination Fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) **$710.00**		
Neither International Preliminary Examination Fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....**$1,000.00**		
International Preliminary Examination Fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....**$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$8600.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	**$0.00**	

Claims	Number Filed	Number Extra	Rate		
Total claims	**15 - 20 =**	**0**	**0 x $18.00**		
Independent claims	**1 - 3 =**	**0**	**0 x $80.00**		
Multiple dependent claims (if applicable)			**+ $270.00**	**$860.00**	
TOTAL OF ABOVE CALCULATIONS =				**$860.00**	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				**$**	
SUBTOTAL =				**$860.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)) +				**$**	
TOTAL NATIONAL FEE =				**$860.00**	
				Amount to be refunded	**$**
				charged	**$860.00**

a. ☐ A check in the amount of $____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 19-2570 in the amount of **$860.00** to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-2570 . A duplicate copy of this sheet is enclosed.

d. ☒ General Authorization to charge any and all fees under 37 CFR 1.16 or 1.17, including petitions for extension of time relating to this application (37 CFR 1.136 (a)(3)).

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:
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Attorney Docket No: C70376

IN THE UNITED STATES INTERNATIONAL EXAMINING AUTHORITY

International Application No.:	PCT/EP00/00559
International Filing Date:	26 January 2000
Priority Date Claimed:	02 February 1999
Applicant for DO/US:	Harry FLEWITT
Title of Invention:	CONTAINER WITH SPACED APART LABEL

Assistant Commissioner of Patents
Box PCT
Washington D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Preliminary to calculating filing fees and examining this application, please amend the application as follows:

IN THE CLAIMS:

Please cancel claims 1 to 15 and add new claims 16-30 as follows:.

--16. A product comprising a double walled container, having a base wall and side walls extending upwardly from the base wall toward an upper mouth opening of the container, and the side walls are in the form of a double wall comprising spaced apart inner and outer walls, made of a plastics material, a label being located on the outer surface of the outer wall, the body having an internal cavity containing a medicament content and being bounded at least in part by the inner wall, wherein that the base wall is a continuous base wall linking the inner and outer walls and closing the space between them.

17. A product according to claim 16, wherein the internal cavity is directly enclosed by parts of the outer wall and is in contact with the outer wall, but the label is applied to a part of the outer wall the inner surface of which is not in contact with the contents.

18. A product according to claim 16 wherein the side walls are in the form of a continuous double wall extending the whole height of the internal cavity from the base wall to the mouth opening.

19. A product according to claim 16 wherein substantially cylindrical inner and outer walls are substantially concentric and coaxial.

20. A product according to claim 16 wherein lower and upper container parts which fit together with a seal which does not allow leakage or contamination of the contents, such lower and upper container parts comprising respective lower and upper inner and outer wall parts of the container which fit together when the upper and lower container parts are fitted together.

21. A product according to claim 16 made of plastics material and having an inner wall thickness ca. 1 - 2 mm, and an outer wall thickness ca. 1 - 2.5 mm.

22. A product according to claim 1 wherein the medicament content is a fluid which incorporates a solvent vehicle.

23. A product according to claim 22 wherein the solvent vehicle is a pharmaceutically acceptable oily vehicle.

24. A product according to claim 23 wherein the oily vehicle is a monoglyceride, phospholipid, or a galactolipid.

25. A product according to claim 23 wherein the oily vehicle is selected from glycerol mono-oleate, glycerol monopalmitate and glycerol monostearate.

26. A product according to claim 22 containing a long-chain digylyceride.

27. A product according to claims 22 containing a fatty acid triglyceride.

28. A product according to claim 27 wherein the fatty acid triglyceride is caprylic / capric triglyceride (Tricaprylin).

29. A product according to claim 16 wherein the medicament content comprises calcium mupirocin, fractionated coconut oil, and glycerol mono-oleate.

30. A product according to claim 16 being a nasal spray container provided with means to deliver its medicament content to the nasal area of a user. --

REMARKS

This Preliminary Amendment is being made upon entry of International Application No. PCT/EP99/00559 into the U.S. national phase of prosecution. Claims 1-15 filed in January 2001, during the international phase have been cancelled and replaced with new claims 16-30. New claims 16-30 are written to comply with proper U.S. format and their addition is supported in the claims and specification as originally filed.

In view of the foregoing, favorable consideration of claims 16-30 are requested, early examination on the merits, and allowance of this application with claims 16-30 are earnestly solicited.

A Version with Markings to Show Changes Made is enclosed.

Respectfully submitted,

Nora Stern-Fernandez

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Since claims 1-15 have been replaced with new claims 16-30, a marked-up version is unnecessary.

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CONTAINER WITH SPACED APART LABEL

This invention relates to containers and in particular to containers with plastics material walls whose contents can undesirably permeate through the container walls or which are sensitive to ingress of material through the container walls. In particularly the invention relates to such containers when used for medicaments.

Plastics, e.g. polyethylene, polypropylene, polyethyleneterphthalate, containers are commonly used to contain medicaments. If a label or shrink sleeve is applied to the outer wall of such a container the adhesive which binds the label or sleeve onto the container surface or alternatively the printing ink which is used when information is printed directly onto the container surface may permeate through the wall thereby contaminating the contents of the container, potentially leading to harmful effects. The term "label" used hereinafter, unless specifically distinguished, includes labels attached by an adhesive, shrink sleeves and matter printed directly onto a container wall.

When the content of the container is a medicament, it may be necessary to conduct a stability study/trial of any new labelling material applied to the container wall so as to ensure that the medicament is not compromised by any aspect of the packaging, including the properties of the adhesive and printing inks. Such trials can be expensive and time-consuming. New adhesives, printing inks or plastics materials may have to be sought which do not give rise to the problem discussed above, although this approach is both time consuming and expensive, particularly if clinical trials are required to prove that the new adhesive or ink does not cause contamination of the contents. Conversely the contents of such a plastic walled container, particularly solvents, may permeate through the walls and may have a deleterious effect on a label on the outer surface of the container e.g. causing a label fixed by adhesive to become detached or to discolour the printing ink. Materials for container walls which are non-permeable are known, in particular glass and metal, but these have the disadvantage of fragility and cost.

US 4367821 discloses a container in which a label is attached to an external skirt spaced apart from a container wall, but possible contents for the container, or

the problems caused by label material permeating through the container wall, are not contemplated.

It is an object of the present invention to at least partly provide a solution to the problem of contamination arising from permeation through a container wall of contaminants such as label adhesives or printing ink(s), and/or permeation in the reverse direction of container contents.

According to a first aspect of this invention a product is provided comprising a container having a body defined by a container wall made of a plastics material, at least part of the container wall comprising spaced apart inner and outer walls, a label being located on the outer surface of the outer wall, the body having an internal cavity containing a medicament content and being bounded at least in part by the inner wall.

The container construction of the invention enables the contents of the container to be directly enclosed by the inner wall, and to be in contact with the inner surface of the inner wall, yet not being vulnerable to contamination by label material such as adhesives or printing ink applied to the outer wall, should this material be liable to permeate through the outer wall. Consequently the adhesive or ink cannot contaminate the contents by penetration of the wall, and vice versa the content cannot penetrate the wall and affect the label.

In some places the internal cavity may be directly enclosed by parts of the outer wall and may be in contact with the outer wall, but the label need not be applied to the outer surface of these parts of the outer wall, but only to those parts of the outer wall the inner surface of which is not in contact with the contents.

In a first embodiment the outer wall of the container may comprise a skirt portion attached to, e.g. integral with or fitted onto, the inner wall, and having a skirt part spaced apart from the inner wall.

This skirt portion may be an upper skirt for example surrounding an upper part of the inner wall. In this embodiment the inner wall may comprise the upper part of the body and may include the mouth opening of the container, for example. the inner wall may define and surround the rim of the mouth opening of the container. The skirt portion may alternatively be a lower skirt surrounding the

lower part, e.g. the bottom of the container body. In this embodiment the container may have both upper and lower skirts.

In this first embodiment the label may be attached to the outer surface of the skirt part, whether an upper or lower skirt, or both upper and lower skirts at a place where the skirt part is spaced apart from the inner wall.

The upper or lower skirt portion may have a label fixed to its outer surface by adhesive or alternatively information may be printed directly onto the skirt portion. The abovementioned upper and lower skirts may depend from a part of the body wall which directly encloses the contents of the container i.e. so that the contents of the container are in direct contact with the inner surface of this part of the body wall, but are not in contact with the inner surface of the upper and/or lower skirt portion.

In a second embodiment the container may be a double walled container, having a base wall and side walls extending upwardly from the base wall toward an upper mouth opening of the container, and the side walls may be in the form of a double wall comprising spaced apart inner and outer walls. Suitably the side walls may be in the form of a continuous double wall extending the whole height of the internal cavity from the base wall to the mouth opening. Such a container may conveniently comprise substantially cylindrical inner and outer walls, which may be substantially concentric and coaxial. The base wall may suitably be a continuous base wall linking the inner and outer walls and closing the space between them. The label may be applied to the outer wall of such a container.

The container may be of any shape appropriate for its intended use, for example generally cylindrical, e.g. bottle shaped. The term "cylindrical" as used herein includes true cylinders i.e. a shape having straight longitudinal sides and a circular cross section, with the longitudinal axis of the cylinder passing through the centre of the circular section, and also distorted cylinders, e.g. shapes with convex bulging longitudinal sides e.g. "barrel" shapes, shapes with concave sides, i.e. wider at the cylinder ends than at a waist. Also the term "cylinder" includes such shapes with oval or oblate circular cross section.

When the container is of generally cylindrical shape, then the upper and lower skirts may also be of generally cylindrical shape e.g. of substantially the same

cross sectional shape as the container. When the container is provided with upper or lower skirts these may be made integrally with the container body or may be separately fitted to the container body, for example by welding or a physical connection such as a snap fit.

The container of the invention may for example be of multi-part construction, e.g. in lower and upper container parts which fit together with a seal which does not allow leakage or contamination of the contents, and such lower and upper container parts may comprise respective lower and upper inner and outer wall parts of the container which fit together when the upper and lower container parts are fitted together. In such a construction the respective upper and lower wall parts may both fit together with such a seal.

The container of this invention may be made of conventional plastics, e.g. polyethylene, polypropylene or polyethyleneterphthalate. Suitable wall thicknesses for the inner wall may be ca. 1 - 2 mm, and for the outer wall ca. 1 - 2.5 mm. The inner wall may benefit from protection from the outer wall and may consequently be relatively thin.

The container of the invention is suitable for a wide variety of medicament contents, particularly fluids such as liquid, gel, cream or paste medicaments i.e. which incorporate a solvent vehicle. Such medicaments may for example be suitable for topical applications or for applications to selected parts of the body e.g. a nasal medicament. Such medicaments may be applied as a spray, droplet or surface smear to such a selected part of the body. Examples of such medicaments are liquid formulations based on known pharmaceutically acceptable oily vehicles such as monoglycerides, such as mono-olein and mono-linolein, phospholipids such as phosphatidyl cholines, and galactolipids such as glyceryl diglycerides. Typically such monoglycerides may be long-chain fatty acid monoglycerides, optionally also containing a long-chain digylyceride. Such mono- and di- glycerides may for example be blends of different long-chain fatty acid mono- and di- glycerides. Examples of such fatty acid monoglycerides include glycerol mono-oleate, glycerol monopalmitate and glycerol monostearate. Suitable commercially available examples of such products include those available under the trade names MYVEROL, such as MYVEROL, MYVATEX, MYVAPLEX and GMORPHIC 80

respectively. Another example of such a material is ARLACEL 186, which in addition to glycerol mono-oleate includes propylene glycol. Typically in such long-chain monoglycerides the major fatty acid component is a C_{18} saturated, mono-unsaturated or polyunsaturated fatty acid. Such oily vehicle based medicaments may also include fatty acid triglycerides, typically a vegetable oil, for example as diluents with the above-mentioned fatty acid monoglycerides. Examples of such include coconut oil, e.g. fractionated coconut oil. Commercially available examples of such triglyceride diluent materials include caprylic / capric triglyceride (Tricaprylin). Examples of such materials which are commercially available include those available under the trade names MYRITOL, CAPTEX and MIGLYOL. Examples of such oily vehicles are for example disclosed in WO98/14189A (SmithKline Beecham PLC) the contents of which are included herein by way of reference. The container of the invention is suitable for use with a wide range of active compounds dissolved or dispersed in such a vehicle. A particular example of such an active compound is the compound the antibiotic Mupirocin (Pseudomonic acid, "Bactroban™ ") typically in the form of calcium mupirocin. An example of such a mupirocin formulation suitable for use as a nasopharyngeal spray formulation is also disclosed in WO98/14189A, typically comprising fractionated coconut oil (i.e. medium chain length triglycerides) e.g. the commercial product MIGLYOL, glycerol mono-oleate e.g. the commercial product MYVEROL 18-99, powdered lemon juice flavour, and micronised calcium mupirocin. The container of the invention is for example provided for, or containing, such a formulation.

The container may be otherwise generally conventional and also provided with a suitable closure means for its mouth opening such as a snap fit or screw threaded cap. The container may further comprise delivery means to deliver fluid contents to for example a nozzle, comprised by the mouth opening of the container, such as a feed tube leading from the mouth opening to the vicinity of the bottom of the container. Such delivery means may comprise for example a pump, typically of a known type used to pump liquid medicaments, such as an air lift pump, leading to an outlet for the medicament such as a spray nozzle.

For example the container may be a nasal spray container provided with means to deliver its medicament content to the nasal area of a user.

The container may be made by conventional methods such as blow moulding or injection moulding. Another aspect of the invention provides moulds for making containers of the present invention and furthermore a process e.g. an injection moulding or blow moulding process using such moulds for making the container of the invention.

The present invention also provides a method of labelling a container wherein a container is provided having a body defined by a container wall made of a plastics material, at least part of the container wall comprising spaced apart inner and outer walls, the body having an internal cavity for containing a medicament formulation content and being bounded at least in part by the inner wall, and a label is applied to the outer surface of the outer wall.

The present invention also provides a method of labelling a container wherein a container is provided having a body defined by a container wall made of a plastics material, at least part of the container wall comprising spaced apart inner and outer walls, the body having an internal cavity for containing a medicament content and being bounded at least in part by the inner wall, and a label is applied to the outer surface of the outer wall, for the purpose of reducing the likelihood of label material permeating through the container wall to contaminate the contents, or for the purpose of reducing the likelihood of contents permeating through the container wall to adversely affect the label..

The container will now be described by way of example only with reference to the accompanying drawing in which Figs.1 and 2 show containers of the invention.

Referring to Fig.1, a container of this invention is shown in longitudinal section. The container comprises a bottle-shaped container 11 of generally cylindrical shape with a generally conical bottom with its concave side toward the interior of the container, defined by a container wall 12. The container 11 is provided with pairs of spaced apart inner and outer walls, being a lower pair of inner 13 and outer 14 walls and an upper pair of inner 15 and outer 16 walls. The outer wall of each of these pairs 13, 14 and 15, 16 respectively is in the form of a lower skirt portion 17 and an upper skirt portion 18. The lower skirt portion 17

depends from the container wall 12 and surrounds the conical bottom of the container 11. This conical bottom consequently comprises the inner wall 13.

A label 19 is attached by adhesive to the outer surface of the outer wall 14. An upper skirt portion 18 extends from the container wall 12 and also has a label 19 applied to it by adhesive. Liquid contents 110 are within the container wall 12. By locating the label 19 only on the outer wall 14 of the lower skirt 17 and/or the upper skirt 18, and not on an outer surface of the container wall 12 of which the inner surface is in contact with the contents 110, the liquid contents 110 and label 19 are consequently not facing each other on opposite sides of the same region of container wall 12. Therefore adhesive from the label 19 cannot permeate through the container wall 12 and contaminate the contents 110 and vice versa the contents 110 cannot leak through container wall 12 and affect the label 19.

The lower skirt portion 17 is made integrally with the container wall 12 and integrally joins the container wall at its upper extremity. The upper skirt portion 18 is made separately and is fitted to the upper part of the container wall 12 by a snap fit fitting at 111.

Alternatively the lower skirt 17 may be made separately and fitted to the container 11 or the upper skirt 18 may be made integrally with the container 11. The container 11 is provided with a mouth opening 112 which has a rim defined by the upper part of the inner wall 15 of the container wall 12. The container 11 is also provided with a delivery means 113 (generally) comprising a nozzle 114 and a feed tube 115. The nozzle 114 fits tightly onto the mouth opening 112 of the container by a snap fitting. The feed tube 115 reaches down toward the lowest part of the conical bottom of the container and feeds liquid to the nozzle 114 from the body 11 in a known manner for example via a pump mechanism 116 or by making the container wall 12 of compressible material and squeezing the container. The container 11 is closed by a closure 117 cover. As shown in the sectional view Fig. 1B about the line B—B the container 11 is oval in cross section.

Referring to Fig. 2 another version of the container of the invention is shown which comprises a lower part container 21 (overall) which has a base wall 22 and lower part side walls 23, 24 extending upwardly from the base wall toward an upper mouth opening 25 of the container 21. The side walls 23, 24 are a continuous

double wall comprising spaced apart inner 23 and outer 24 walls extending from the base wall 22 to the height of the mouth opening 25. The inner 23 and outer 24 are substantially cylindrical (as seen in Fig. 2B having an oval cross section, and are substantially concentric and coaxial. The base wall 22 is a continuous base wall linking the inner 23 and outer 24 walls and closing the space 26 between them. The container construction of the invention enables contents (not shown) in the internal cavity 27 of the container to be directly enclosed by the inner wall 23, and to be in contact with the inner surface of the inner wall 23, yet not being vulnerable to contamination by label materials 28 such as adhesives or printing ink applied to the outer wall 24. The internal cavity 27 is also directly enclosed by the base wall 22 where this forms a part of the outer wall 24, but the label is not applied to the outer surface of the base wall 22. The container 21 is made of polypropylene and the inner wall is ca. 1 – 1.5 mm thick, and the outer wall ca. 1.5 - 2.0 mm thick. The volume of the internal cavity 27 is ca 10 – 25 ml in the example illustrated.

The container 21 is suitable for a liquid medicament which incorporates a solvent vehicle, such as the oily vehicles described above. As shown the container 21 is a nasal spray dispenser. The container is provided with a pump 29 (generally), typically an air lift pump, to deliver liquid contents to a nozzle 210, via a feed tube leading from the mouth opening to the vicinity of the bottom of the container. The pump 29 is provided as part of an upper part assembly 212 (generally), including upper part inner and outer walls respectively 23A and 24A, and provided with fittings 213A enabling it to fit by a push action onto the lower part container 21 at corresponding fittings 213B, and to be retained thereon by a friction and snap fit. The fitting together of the fittings 213A and 213B form a seal which prevents leakage and contamination of the contents in the cavity 27.

The nozzle 210 is covered by a cover closure 214 such that the feed tube 211 fits into the cavity 27 and reaches down to a point near its bottom. As shown in the half sectional view Fig. 2B about the line B—B the container 21 is oval in cross section.

EPT ON ABSTR

Claims PCT Amended January 2001

1. A product comprising a double walled container (21), having a base wall (22) and side walls (23,24) extending upwardly from the base wall (22) toward an upper mouth opening (25) of the container, and the side walls (23,24) are in the form of a double wall comprising spaced apart inner (23) and outer (24) walls, made of a plastics material, a label (28) being located on the outer surface of the outer wall (24), the body (21) having an internal cavity (27) containing a medicament content and being bounded at least in part by the inner wall (23), *characterised* in that the base wall (22) is a continuous base wall (22) linking the inner and outer walls (23,24) and closing the space (26) between them.

2. A product according to claim 1, characterised in that the internal cavity (27) is directly enclosed by parts of the outer wall (24) and is in contact with the outer wall (24), but the label (28) is applied to a part of the outer wall (24) the inner surface of which is not in contact with the contents.

3. A product according to claim 1 or 2 *characterised* in that the side walls (23,24) are in the form of a continuous double wall (23,24) extending the whole height of the internal cavity (27) from the base wall (22) to the mouth opening (25).

4. A product according to any preceding claim *characterised* by substantially cylindrical inner and outer walls (23,24), which are substantially concentric and coaxial.

5. A product according to any preceding claim *characterised* by lower (21) and upper (212) container parts which fit together with a seal (213A,213B) which does not allow leakage or contamination of the contents, such lower and upper container parts (21, 212) comprising respective lower (23,24) and upper (23A,24A) inner and outer wall parts of the container which fit together when the upper (23A,24A) and lower (23,24) container parts are fitted together.

AMENDED SHEET

6. A product according to any preceding claim made of plastics material and having an inner wall (23) thickness ca. 1 - 2 mm, and an outer wall thickness ca. 1 - 2.5 mm.

7. A product according to any preceding claim *characterised* in that the medicament content is a fluid which incorporates a solvent vehicle.

8. A product according to claim 7 *characterised* in that the solvent vehicle is a pharmaceutically acceptable oily vehicle.

9. A product according to claim 8 *characterised* in that the oily vehicle is a monoglyceride, phospholipid, or a galactolipid.

10. A product according to claim 9 *characterised* in that the oily vehicle is selected from glycerol mono-oleate, glycerol monopalmitate and glycerol monostearate.

11. A product according to claim 8, 9 or 10 *characterised* by containing a long-chain digylyceride.

12. A product according to any one of claims 8 to 10 containing a fatty acid triglyceride.

13. A product according to claim 12 *characterised* in that the fatty acid triglyceride is caprylic / capric triglyceride (Tricaprylin).

14. A product according to any one of the preceding claims *characterised* in that the medicament content comprises calcium mupirocin, fractionated coconut oil, and glycerol mono-oleate.

15. A product according to any preceding claim being a nasal spray container (21) provided with means (29,210) to deliver its medicament content to the nasal

area of a user.

AMENDED SHEET

Fig-1

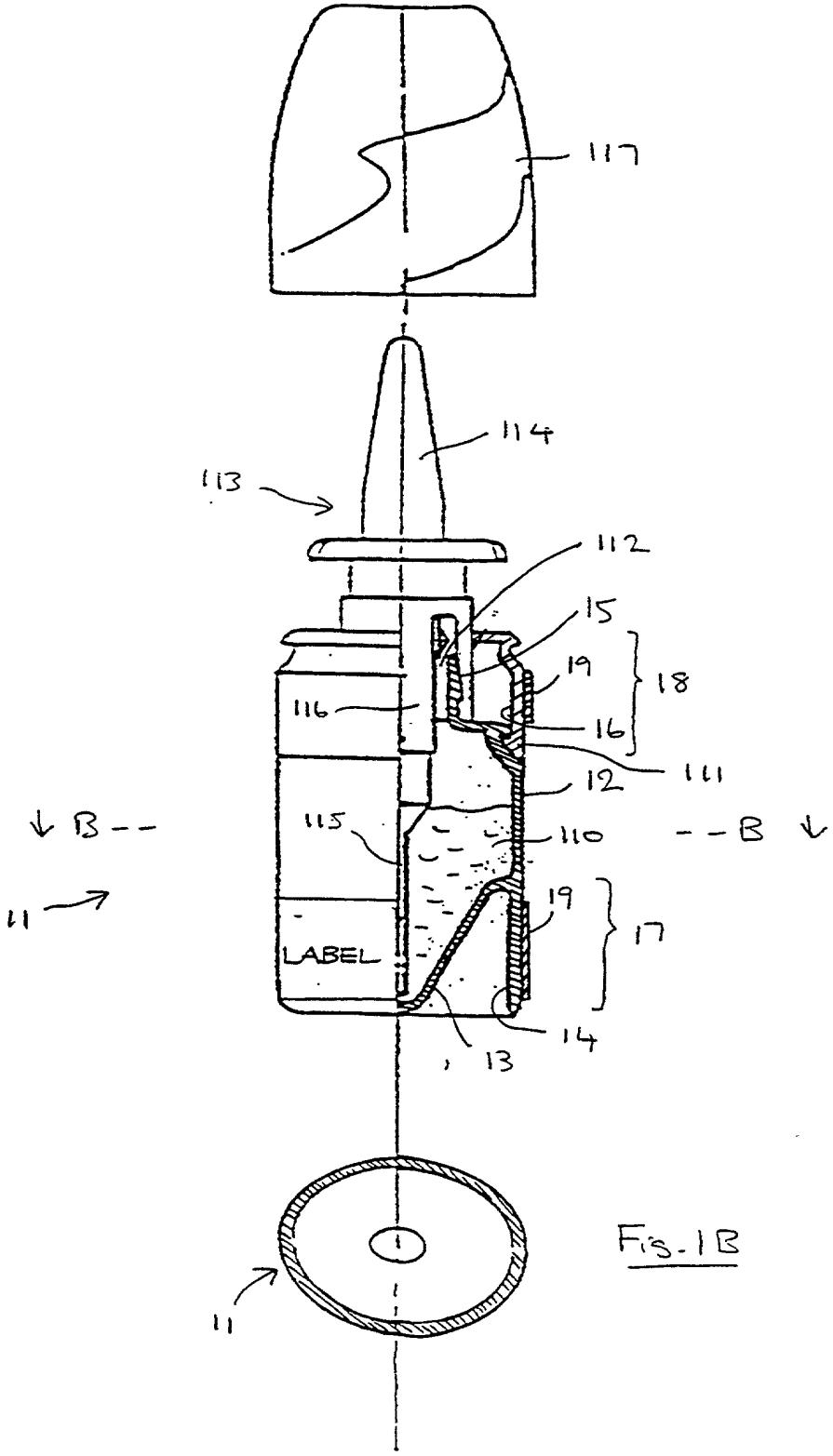
117
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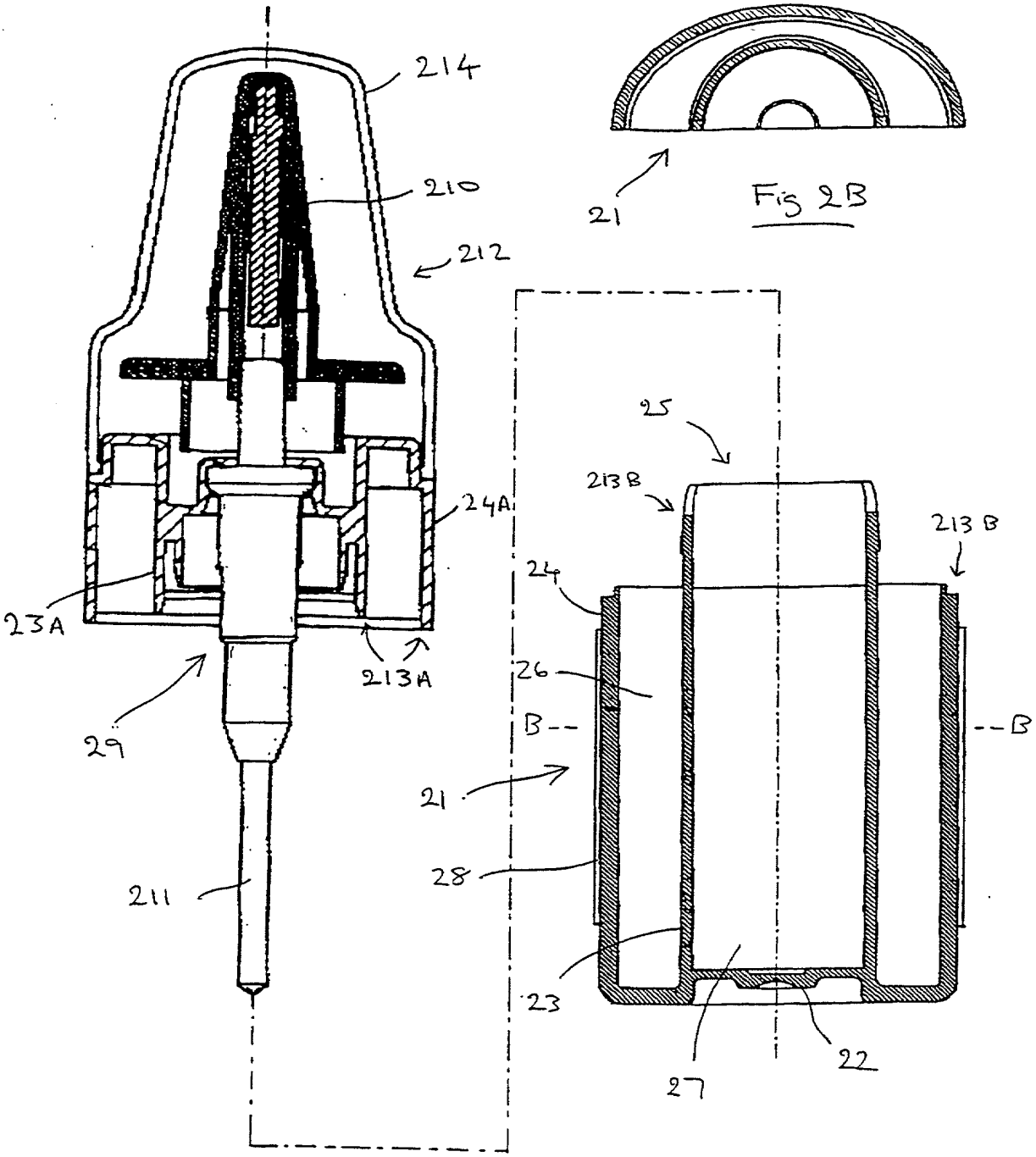
Fig-1B


214
210
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24A
23A
213A
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Fig 2B
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213B
213B
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Fig. 2

Docket No.: C70376 PCT/EP00/00559

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CONTAINER WITH SPACED APART LABEL

the specification of which (check one)

[ ] is attached hereto.

[X] was filed on 26 January 2000 as Serial No. PCT/EP00/00559
and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or Inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Number	Country	Filing Date	Priority Claimed
9902138.8	Great Britain	02 February 1999	Yes

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below.

Application Number	Filing Date

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Serial No. Filing Date Status

I hereby appoint the practitioners associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to that Customer Number:

Customer Number 20462.

Address all correspondence and telephone calls to Nora Stein-Fernandez, GlaxoSmithKline, Corporate Intellectual Property-U.S., UW2220, P.O. Box 1539, King of Prussia, Pennsylvania 19406-0939, whose telephone number is 610-270-5044.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

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